**AUB KQ1 Evidence Table (Reference ID #1431)**

| **Study Description** | **Intervention(s)/ Comparator(s)** | **Patient Population** | **Baseline Measure(s)a** | **Outcome Measure(s)** | **Overall Quality**  **Risk of Bias** |
| --- | --- | --- | --- | --- | --- |
| **Author:**  Elkind-Hirsch et al., 2008  **Country:**  United States  **Enrollment** **period:**  August 2006 to June 2007  **Intervention** **setting:**  Outpatient clinics  **Funding:**  Amylin Pharmaceuticals, Inc/Eli Lilly Corp  **Author industry relationship disclosures:**  2/5  **Study Design:**  RCT  **Blinding:**  None | **Intervention:**  Exenatide 5 µg by subcutaneous injection twice a day and increased to 10 µg twice per day after 1 month.  **Comparator:**  Metformin 500 mg for two weeks and gradually increased to 1000 mg twice a day;  Combination: metformin 500 mg for two weeks and gradually increased to 1000 mg twice a day plus exenatide 5 µg by subcutaneous injection twice a day and increased to 10 µg twice per day after 1 month.  All groups received treatment for 24 weeks.  **Groups:**  **G1:** Exenatide  **G2:** Metformin  **G3:** Combination metformin and exenatide  **Followup:**  24 weeks | **Inclusion criteria:**  Aged 18 to 40 years  Polycystic ovary syndrome  Overweight/obese (BMI >27)  Menstrual disorders (fewer than six menstruations in 12 months)  One of the following two criteria:  either clinical and/or biochemical hyperandrogenism  (excluding secondary causes) and/or polycystic ovaries  **Exclusion criteria:**  Diabetics  Smokers  Those who used injectable hormonal contraceptive within 6 months  Those taking sex hormones, drugs that affect gastrointestinal motility or carbohydrate metabolism, or lipid-lowering and/or anti-obesity drugs within 3 months of  the study  **N at enrollment:**  **G1:** 20  **G2:** 20  **G3:** 20  **N at followup:**  **G1:** 14  **G2:** 14  **G3:** 14  **Age, mean years ± SD:**  **G1:** 28.2 ± 1.1  **G2:** 27.7 ± 1.3  **G3:** 32.1 ± 0.7  **G1 vs. G2 vs. G3:** p=NS  **BMI, mean kg/m2 ± SD:**  **G1:** 39.9 ± 1.5  **G2:** 41.3 ± 1.8  **G3:** 41.2 ± 1.7  **G1 vs. G2 vs. G3:** p=NS  **Parity:**  NR  **Race, n (%):**  Caucasian:  **G1+G2+G3:** 40 (67)  African-American:  **G1+G2+G3:** 20 (33) | **Bleeding:**  Cycle changes measured by menstrual frequency index,b mean ± SD:  **G1:** 0.22 ± 0.04  **G2:** 0.21 ± 0.04  **G3**: 0.29 ± 0.04  Absolute weight, mean kg ± SD:  **G1:** 110.5 ± 6  **G2:** 113.4 ± 7  **G3:** 112 ± 8  Abdominal girth, mean cm ± SD:  **G1:** 120.4 ± 4.5  **G2:** 123.4 ± 4.3  **G3:** 122 ± 4.4  BMI, mean kg/m2 ± SD:  **G1:** 40.3 ± 2  **G2:** 43.3 ± 2  **G3:** 40.9 ± 2 | **Bleeding:**  Cycle changes measured by menstrual frequency index,b mean ± SD:  **G1:** 0.57 ± 0.08  **G2:** 0.49 ± 0.08  **G3:** 0.83 ± 0.08  **G1+G2+G3 vs. BL:** p=0.0001  **G3 vs. G1:** p=0.091  **G3 vs. G2:** p=0.018  Ovulatory rate,%:  **G1:** 50  **G2:** 29  **G3:** 86  **G3 vs. G1:** p<0.001  **G3 vs. G2**: p<0.001  **Weight changes:**  Weight loss, mean kg ± SD:  **G1:** 3.2 ± 0.1  **G2:** 1.6 ± 0.2  **G3:** 6 ± 0.5  **G1+G2+G3 vs. BL:** p=0.001  **G1 vs. G2:** p=0.019  **G3 vs. G2:** p=0.003  Abdominal girth, mean ± SD:  **G1:** 119.6 ± 4.3  **G2:** 123.9 ± 4.4  **G3:** 116 ± 4.3  **G1+G2+G3 vs. BL:** p=0.047  **G3 vs. G2:** p=0.04  BMI, mean kg/m2 ± SD:  **G1:** 39.3 ± 2  **G2:** 42.3 ± 2  **G3:** 39.2 ± 2  **G1+G2+G3 vs. BL:** p<0.0001  **Quality of life:**  NR  **Pain:**  NR  **Sexual function:**  NR  **Patient satisfaction:**  NR  **Fertility:**  NR  **Time to conception:**  NR  **Additional interventions:**  NR  **Adverse events, n (%):**  Nausea:  **G1:** 3 (15)  **G2:** 4 (20)  **G3:** 9 (45)  Diarrhea:  **G1:** 0  **G2:** 6 (30)  **G3:** 2 (20)  Bloating:  **G1:** 0  **G2:** 2 (10)  **G3:** 1 (5)  Vomiting:  **G1:** 1 (5)  **G2:** 1 (5)  **G3:** 2 (10)  Cramping (gastrointestinal):  **G1:** 1 (5)  **G2:** 0  **G3:** 0  Headache:  **G1:** 1 (5)  **G2:** 0  **G3:** 0  Indigestion/heartburn:  **G1:** 0  **G2:** 0  **G3:** 2 (10)  Stomachache:  **G1:** 0  **G2:** 1 (5)  **G3:** 0  Constipation:  **G1:** 0  **G2:** 1 (5)  **G3:** 1 (5)  Fatigue:  **G1:** 0  **G2:** 2 (10)  **G3:** 1 (5)  Dizzy:  **G1:** 0  **G2:** 0  **G3:** 2 (10)  Injection site pain/bruise:  **G1:** 1 (5)  **G2:** NA  **G3:** 2 (10)  Pregnancy:  **G1:** 1 (5)  **G2:** 2 (10)  **G3:** 1 (5)  Menstrual cramps:  **G1:** 0  **G2:** 1 (5)  **G3:** 0  Dysfunctional menstrual bleeding:  **G1:** 1 (5)  **G2:** 1 (5)  **G3:** 0  Acne:  **G1:** 0  **G2:** 0  **G3:** 1 (5)  Migraines:  **G1:** 0  **G2:** 1 (5)  **G3:** 0  Hot flashes:  **G1:** 0  **G2:** 1 (5)  **G3:** 0 | **Overall quality:** Poor  **Risk of bias:**  Randomization:  Low  Allocation concealment:  Unclear  Selective reporting:  Low  Blinding patients/personnel:  High  Blinding outcome assessment:  High  Incomplete outcome reporting:  High  Other:  Low |

**Table Notes:** a Baseline measures for the subset of subjects who competed the trial (n=14 in each group); b Cycle event rate (normalized to 12 per 52 weeks)